without serious burden, the examiner **must** examine it on the merits, **even though** it includes claims to independent or distinct inventions." (MPEP § 803, emphasis added). "There are two criteria for a proper requirement for restriction between two patentably distinct inventions: (A) The inventions must be independent or distinct as claimed; **and** (B) There must be a serious burden on the examiner if restriction is required." (*Id.*, emphasis added, citations omitted). *Id.* Applicants urge that the Examiner has offered no evidence to satisfy either part (A) or part (B), both of which require a showing for the restriction to be proper.

# Inventions are not Independent Under MPEP § 806.04(A)

The Examiner has stated restriction is proper because "[I]nventions I, II, III, and IV are unrelated." To justify this position, she quotes MPEP § 806.04(A) and states inventions are unrelated if they are "not disclosed as capable of use together **and** they have different modes of operation, different functions or different effects." (Emphasis added). Yet, the Examiner does not provide any factual evidence that the inventions (1) are incapable of use together or (2) have different modes of operation, function or effect.

Instead, she states "the inventions have separate searchable limitations" and have "a plurality of patentably distinct species." These statements are not evidence of the inventions being incapable of use together and having different modes of operation, function or effect. Indeed, all of the present gylcopeptides are capable of use together and have related modes of operation, function and effect.

MPEP § 806.04(A) is illustrative of independent inventions: "[A]n article of apparel such as a shoe and a locomotive bearing would be an example." In striking contrast to this example, all of the pending claims are directed to a "glycopeptide"

In conclusion, the Examiner has failed to meet either prong of the two-part showing required under MPEP § 806.04(A) for independent inventions, and therefore restriction between Groups I, II, III, and IV is improper.

### The Claims Recite Only One Sequence Identification Number

The Examiner states from an undisclosed source that "[R]esources are now stretched to the limit, such that only one sequence should be searched per application," however, the only sequence identification number recited in the claims is SEQ ID NO 2. Thus, as only one sequence identification number is recited in the claims, further restriction among sequence identification numbers is literally impossible.

#### The Examiner has Admitted the Classification for All Claims is Identical

The Examiner has admitted that all groups can be searched within the same classes and subclasses: 530/322 and 530/395. This is in contradiction with the Examiner's subsequent statement at page 4 of the Office Action of "different classification" necessitating restriction. As all of the claims recite a glycopeptide, the search classification for all claims should be the same. Again, the Examiner has failed to present factual evidence of a proper restriction.

### The Examiner Has Not and Cannot Demonstrate a "Serious Burden"

Because this search can be done within the same classes for SEQ ID NO 2, applicants respectfully contend that the examiner has not demonstrated "a serious burden," even if the claims have distinct recitations to gylcosylation, homology, amino acid length etc. Therefore applicants request reconsideration and withdraw of the present restriction requirement.

Respectfully submitted,

October 29, 2001

Date:

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

## Marked-Up Version of the Amended Claims

44. (Twice Amended) A purified glycopolypeptide of 65kd to 100kd that can bind human spermatozoa at a glycopolypeptide concentration below 1 μg/ml and induce an acrosome reaction within one hour upon binding, wherein said glycopolypeptide comprises an amino acid sequence that is more than 54% homologous to the following sequence **SEQ ID NO 2**:

SerTrpPheProValGlnGlyProAlaAspIleCysGlnCysCysAsnLysGly AspCysGlyThrProSerHisSerArgArgGlnProHisValMetSerGlnTrpS erArgSerValSer.

45. (Once Amended) A glycopolypeptide comprising between 41 and 400 amino acid that can bind human spermatozoa at a glycopolypeptide concentration below 1 μg/ml and induce an acrosome reaction within one hour upon binding, wherein said glycopolypeptide comprises an amino acid sequence that is at least 54% homologous to the following sequence SEQ ID NO 2:

SerTrpPheProValGlnGlyProAlaAspIleCysGlnCysCysAsnLysGly AspCysGlyThrProSerHisSerArgArgGlnProHisValMetSerGlnTrp SerArgSerValSer,

and wherein the fifth amino acid residue from the carboxyl terminus of said amino acid sequence of said glycopolypeptide is O-glycosylated.

46. (Once Amended) The glycopolypeptide of claim 45, wherein said glycopolypeptide comprises an amino acid sequence that is at least 75% homologous to the following sequence **SEQ ID NO 2**:

 $Ser Trp Phe Pro Val Gln Gly Pro Ala Asp I le Cys Gln Cys Cys Asn Lys Gly \\ Asp Cys Gly Thr Pro Ser His Ser Arg Arg Gln Pro His Val Met Ser Gln Trp Ser Arg Ser Val Ser.$ 

47. (Twice Amended) The glycoprotein of claim 45, wherein the glycoprotein comprises the following amino acid sequence <u>SEQ ID NO 2</u>:
SerTrpPheProValGlnGlyProAlaAspIleCysGlnCysCysAsnLysGlyAspCysGlyThrPro
SerHisSerArgArgGlnProHisValMetSerGlnTrpSerArgSerValSer.